



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC 19 1997 1496 '98 FEB 18 A8 :03

Ms. Gale **Bensussen**
President
Leiner Health Products
901 E. 233rd Street
Carson, California 90745-6204

Dear Ms. **Bensussen**:

This is in response to your letter of October 26, 1997 to the Food and Drug Administration (**FDA**) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that **Leiner** Health Products is making the claim "Garlic is a natural source of **allicin**, which is thought to reduce cholesterol" for the product "Your Life Daily Garlic. "

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, cure, mitigate, or prevent disease, namely **hypercholesterolemia**. This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for use as a drug within the meaning of section 201 Q(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (**CDER**), Office of Compliance, HFD-310, 7520 Standish Place, **Rockville**, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritional
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Los Angeles District Office, Compliance Branch, HFR-PA240

975-0163

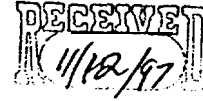
LET99



901 E. 213rd Street
C. 115(17), California
90745-6204
310/835-8400
Fax 310/835-6615

October 26, 1997

Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street S.W.
Washington, D.C. 20204



Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **LEINER HEALTH PRODUCTS** notifies the FDA that it has begun using the following phrase and statements:

Garlic is a natural source of allicin, which is thought to reduce cholesterol.

on the following product:

Your Life® Daily Garlic

Very truly yours,

LEINER HEALTH PRODUCTS

A handwritten signature in dark ink, appearing to read 'Gale Bensussen', written over a horizontal line.

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs
William Cochran, Regulatory Affairs Associate

55701